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09/899,922	07/09/2001	Amanda Johanne Kiliaan	BO 44633	5229

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	8

DATE MAILED: 08/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/899,922	Applicant(s) KILIAAN ET AL.	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment has been received and entered into the case. Claims 1 – 25 have been cancelled. Claims 26 – 40 have been added and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 26 – 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide support for the recitation of "gamma-3" and "gamma-6" fatty acids as originally filed.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 26 – 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26, dependents thereof and 30 are drawn to preventing and treating depression however are rendered vague and indefinite for reciting "gamma-3 fatty acid" and "gamma-6 fatty acid" as phrases are not adequately defined by the specification.

Claims 27 – 29 and 33 – 38 are rendered vague and indefinite because it is unclear if the compositions rather comprise the recited limitations, or further comprise the recited limitations. Applicant may prefer to insert the term "further" after the term "preparation" in lines 2, to more clearly claim the invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 26, 30, 32, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin (WO 98/48788), Naito (Derwent 1995-015698), and Bormann (Derwent 1992-408041).

Applicant claims a method for treating and/or preventing depression and depression related disorders comprising orally administering a composition comprising (a) long chain polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) at least one compound selected from folate, vitamin B12, B6, magnesium, zinc. The omega-3 fatty acids are selected from eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA); the omega-6 fatty acids are selected from arachidonic acid (ARA) and dihomogamma linolenic acid (DGLA). The (c) portion contains both folate and vitamin B6, the composition further comprises at least one of vitamin C, E, lipoic acid, selenium salt or carotenoids, and the composition further comprises vitamin D.

Horrobin teaches compositions for treating depression comprising DHA, ascorbic acid (vitamin C), beta carotene, vitamin B6, zinc, vitamin E and selenium (p.7,Table 3). Specifically, Horrobin teaches DHA (omega 3 fatty acid) can treat depression in doses of at least 350 mg/day (p.4). EPA, linoleic acid (omega 6), dihomogamma linolenic (omega 6) and arachidonic acid are also added to the antidepressant composition at 250 – 2000 mg/day (p.6). The compositions

further contain lipoic acid (p.6) and folic acid, described as valuable nutrients in depression (p.8). Horrobin provides examples comprising vitamin D and magnesium (p.8, examples).

Naito et al. teaches phosphatidylethanolamine is used for treating depression (abstract). Bormann et al. teaches phosphatidylserine is used for treating depression disorders (abstract).

The above references do not teach a method for treating depression or related disorders by administering the claimed composition. However, as demonstrated by the cited references, each of the claimed ingredients were well known in the art for their claimed purpose. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the known antidepressants in a method for treating/preventing depression with a reasonable expectation of success, given the known antidepressant characteristics of the components. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients in a method for treating depression, since they were each well known antidepressants, as evidenced by the cited references.

8. Claims 26, 30 – 33, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Naito, Bormann and Stoll et al. (US 6344482 B1).

Applicant claims a method for treating and/or preventing depression and depression related disorders comprising orally administering a composition comprising (a) long chain polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) at least one

compound selected from folate, vitamin B12, B6, magnesium, zinc. The omega-3 fatty acids are selected from eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) and the omega-6 fatty acids are selected from arachidonic acid (ARA) and dihomogamma linolenic acid (DGLA). The (b) portion comprises phosphatidylcholine, phosphatidylethanolamine and phosphatidylserine; the (c) portion contains both folate and vitamin B6. The composition further comprises at least one of SAMe, choline, betaine or copper, at least one of vitamin C, E, lipoic acid, selenium salt or carotenoids and further comprises vitamin D.

Horrobin teaches compositions for treating depression comprising DHA, ascorbic acid (vitamin C), beta carotene, vitamin B6, zinc, vitamin E and selenium (p.7,Table 3). Specifically, Horrobin teaches DHA (omega 3 fatty acid) can treat depression in doses of at least 350 mg/day (p.4). EPA, linoleic acid (omega 6), dihomogamma linolenic (omega 6) and arachidonic acid are also added to the antidepressant composition at 250 – 2000 mg/day (p.6). The compositions further contain lipoic acid (p.6) and folic acid, described as valuable nutrients in depression (p.8). Horrobin provides examples comprising vitamin D and magnesium (p.8, examples).

Naito et al. teaches phosphatidylethanolamine is used for treating depression (abstract). Bormann et al. teaches phosphatidylserine is used for treating depression disorders (abstract).

Stoll et al. teaches treating bipolar disorder (mania and depression) by administering omega 3 fatty acids (abstract), specifically phosphatidylcholine (col.1 line 46-52), EPA and/or DHA (col.2 line 23-29) and choline (col.2 line 12-13).

The above references do not teach a method for treating depression or related disorders by administering the claimed composition. However, as demonstrated by the cited references, each of the claimed ingredients were well known in the art for their claimed purpose. At the

time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the known antidepressants in a method for treating/preventing depression with a reasonable expectation of success, given the known antidepressant characteristics of the components. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients in a method for treating depression, since they were each well known antidepressants, as evidenced by the cited references.

9. Claims 26, 27, 30, 32, 35, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Naito, Bormann and Cavazza (WO 99/66914).

Applicant claims a method for treating and/or preventing depression and depression related disorders comprising orally administering a composition comprising (a) long chain polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) at least one compound selected from folate, vitamin B12, B6, magnesium, zinc. The composition further comprises hypericin or an extract of Withania somnifera. The omega-3 fatty acids are selected from eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) and the omega-6 fatty acids are selected from arachidonic acid (ARA) and dihomogamma linolenic acid (DGLA). The (c) portion contains both folate and vitamin B6. The composition further comprises at least one of carnitine, vitamin B1, B5, coenzyme Q10; further comprises at least one of vitamin C, E, lipoic acid, selenium salt or carotenoids; or further comprises vitamin D.

Horrobin teaches compositions for treating depression comprising DHA, ascorbic acid (vitamin C), beta carotene, vitamin B6, zinc, vitamin E and selenium (p.7,Table 3). Specifically, Horrobin teaches DHA (omega 3 fatty acid) can treat depression in doses of at least 350 mg/day (p.4). EPA, linoleic acid (omega 6), dihomogamma linolenic (omega 6) and arachidonic acid are also added to the antidepressant composition at 250 – 2000 mg/day (p.6). The compositions further contain lipoic acid (p.6) and folic acid, described as valuable nutrients in depression (p.8). Horrobin provides examples comprising vitamin D and magnesium (p.8, examples).

Naito et al. teaches phosphatidylethanolamine is used for treating depression (abstract). Bormann et al. teaches phosphatidylserine is used for treating depression disorders (abstract).

Cavazza teaches compositions and methods for treating depression comprising carnitines and hypericin (abstract).

The above references do not teach a method for treating depression or related disorders by administering the claimed composition. However, as demonstrated by the cited references, each of the claimed ingredients were well known in the art for their claimed purpose. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the known antidepressants in a method for treating/preventing depression with a reasonable expectation of success, given the known antidepressant characteristics of the components. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients in a method for treating depression, since they were each well known antidepressants, as evidenced by the cited references.

10. Claims 26, 29, 30, 32, 33, 34, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Naito, Bormann and Pollack et al. (US 4897380).

Applicant claims a method for treating and/or preventing depression and depression related disorders comprising orally administering a composition comprising (a) long chain polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) at least one compound selected from folate, vitamin B12, B6, magnesium, zinc. The composition further comprises tryptophan or a protein containing tryptophan. The omega-3 fatty acids are selected from eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) and the omega-6 fatty acids are selected from arachidonic acid (ARA) and dihomogamma linolenic acid (DGLA). The (c) portion contains both folate and vitamin B6; the composition further comprises at least one of SAMe, choline, betaine or copper; further comprises zinc and copper in weight ratio between 5 – 12; further comprises at least one of vitamin C, E, lipoic acid, selenium salt or carotenoids; or further comprises vitamin D.

Horrobin teaches compositions for treating depression comprising DHA, ascorbic acid (vitamin C), beta carotene, vitamin B6, zinc, vitamin E and selenium (p.7,Table 3). Specifically, Horrobin teaches DHA (omega 3 fatty acid) can treat depression in doses of at least 350 mg/day (p.4). EPA, linoleic acid (omega 6), dihomogamma linolenic (omega 6) and arachidonic acid are also added to the antidepressant composition at 250 – 2000 mg/day (p.6). The compositions further contain lipoic acid (p.6) and folic acid, described as valuable nutrients in depression (p.8). Horrobin provides examples comprising vitamin D and magnesium (p.8, examples).

Naito et al. teaches phosphatidylethanolamine is used for treating depression (abstract). Bormann et al. teaches phosphatidylserine is used for treating depression disorders (abstract).

Pollack et al. teaches methods for treating depression comprising administering compositions comprising L-tryptophan, B6 (pyridoxine), vitamin C (ascorbic acid), copper and magnesium (abstract, claims 8-14).

The above references do not teach a method for treating depression or related disorders by administering the claimed composition. However, as demonstrated by the cited references, each of the claimed ingredients were well known in the art for their claimed purpose. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the known antidepressants in a method for treating/preventing depression with a reasonable expectation of success, given the known antidepressant characteristics of the components. Although the references do not teach a specific ration between zinc and copper, it would have been obvious to optimize amounts since it was routine practice in the art at the time the claimed invention was made. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients in a method for treating depression, since they were each well known antidepressants, as evidenced by the cited references.

11. Claims 26, 27, 30, 32, 33, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Naito, Bormann and Desantis et al. (US 6096317).

Applicant claims a method for treating and/or preventing depression and depression related disorders comprising orally administering a composition comprising (a) long chain

polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) at least one compound selected from folate, vitamin B12, B6, magnesium, zinc. The composition further comprises hypericin or an extract of Withania somnifera. The omega-3 fatty acids are selected from eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) and the omega-6 fatty acids are selected from arachidonic acid (ARA) and dihomogamma linolenic acid (DGLA). The (c) portion contains both folate and vitamin B6; the composition further comprises at least one of SAMe, choline, betaine or copper; further comprises at least one of vitamin C, E, lipoic acid, selenium salt or carotenoids; or further comprises vitamin D.

Horrobin teaches compositions for treating depression comprising DHA, ascorbic acid (vitamin C), beta carotene, vitamin B6, zinc, vitamin E and selenium (p.7,Table 3). Specifically, Horrobin teaches DHA (omega 3 fatty acid) can treat depression in doses of at least 350 mg/day (p.4). EPA, linoleic acid (omega 6), dihomogamma linolenic (omega 6) and arachidonic acid are also added to the antidepressant composition at 250 – 2000 mg/day (p.6). The compositions further contain lipoic acid (p.6) and folic acid, described as valuable nutrients in depression (p.8). Horrobin provides examples comprising vitamin D and magnesium (p.8, examples).

Naito et al. teaches phosphatidylethanolamine is used for treating depression (abstract). Bormann et al. teaches phosphatidylserine is used for treating depression disorders (abstract).

Desantis et al. teaches Hypericum (hypericin) and methyl donors, such as SAMe, treat depression (abstract). Desantis teaches that other methyl donors are also effective, including choline, betaine and vitamin B12 (col.2 line 58-62). Deficiencies in folic acid, vitamins B6, B12

and C are disclosed to contribute to depression, and adding these ingredients to antidepressant compositions is recommended (col.2 line27-30,44-46). Desantis specifically teaches a method for treating depression comprising administering compositions comprising hypericum (hypericin), methyl donors, folic acid and vitamins B6, B12 and C (claims 10-15).

The above references do not teach a method for treating depression or related disorders by administering the claimed composition. However, as demonstrated by the cited references, each of the claimed ingredients were well known in the art for their claimed purpose. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the known antidepressants in a method for treating/preventing depression with a reasonable expectation of success, given the known antidepressant characteristics of the components. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients in a method for treating depression, since they were each well known antidepressants, as evidenced by the cited references.

12. Claims 26, 27, 30, 32 and 36 – 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Naito, Bormann and Bewicke (US 5820867).

Applicant claims a method for treating and/or preventing depression and depression related disorders comprising orally administering a composition comprising (a) long chain polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) at least one

compound selected from folate, vitamin B12, B6, magnesium, zinc. The composition further comprises hypericin or an extract of Withania somnifera. The omega-3 fatty acids are selected from eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) and the omega-6 fatty acids are selected from arachidonic acid (ARA) and dihomogamma linolenic acid (DGLA). The (c) portion contains both folate and vitamin B6. The composition further comprises at least one of vitamin C, E, lipoic acid, selenium salt or carotenoids; further comprises ginkgo biloba extract; or further comprises vitamin D.

Horrobin teaches compositions for treating depression comprising DHA, ascorbic acid (vitamin C), beta carotene, vitamin B6, zinc, vitamin E and selenium (p.7,Table 3). Specifically, Horrobin teaches DHA (omega 3 fatty acid) can treat depression in doses of at least 350 mg/day (p.4). EPA, linoleic acid (omega 6), dihomogamma linolenic (omega 6) and arachidonic acid are also added to the antidepressant composition at 250 – 2000 mg/day (p.6). The compositions further contain lipoic acid (p.6) and folic acid, described as valuable nutrients in depression (p.8). Horrobin provides examples comprising vitamin D and magnesium (p.8, examples).

Naito et al. teaches phosphatidylethanolamine is used for treating depression (abstract). Bormann et al. teaches phosphatidylserine is used for treating depression disorders (abstract).

Bewicke teaches antidepressant compositions comprising hypericin, ginkgo extracts, vitamins B6, B12, C and folic acid (abstract). Specifically, Bewicke teaches hypericin relieves depression (col.1 line 45-51), ginkgo is an anti-depressant (col.2 line50-56), and that deficiencies of vitamin B6, B12 and folic acid causes depression (col.2 line 58-col.3 line 6).

The above references do not teach a method for treating depression or related disorders by administering the claimed composition. However, as demonstrated by the cited references,

each of the claimed ingredients were well known in the art for their claimed purpose. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the known antidepressants in a method for treating/preventing depression with a reasonable expectation of success, given the known antidepressant characteristics of the components. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients in a method for treating depression, since they were each well known antidepressants, as evidenced by the cited references.

13. Claims 26, 30, 32, 35, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Naito, Bormann and Oberthur et al. (US 6369042).

Applicant claims a method for treating and/or preventing depression and depression related disorders comprising orally administering a composition comprising (a) long chain polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) at least one compound selected from folate, vitamin B12, B6, magnesium, zinc. The omega-3 fatty acids are selected from eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) and the omega-6 fatty acids are selected from arachidonic acid (ARA) and dihomogamma linolenic acid (DGLA). The (c) portion contains both folate and vitamin B6. The composition further comprises at least one of carnitine, vitamin B1, B5, coenzyme Q10; further comprises at least one of vitamin C, E, lipoic acid, selenium salt or carotenoids; or further comprises vitamin D.

Horrobin teaches compositions for treating depression comprising DHA, ascorbic acid (vitamin C), beta carotene, vitamin B6, zinc, vitamin E and selenium (p.7,Table 3). Specifically, Horrobin teaches DHA (omega 3 fatty acid) can treat depression in doses of at least 350 mg/day (p.4). EPA, linoleic acid (omega 6), dihomogamma linolenic (omega 6) and arachidonic acid are also added to the antidepressant composition at 250 – 2000 mg/day (p.6). The compositions further contain lipoic acid (p.6) and folic acid, described as valuable nutrients in depression (p.8). Horrobin provides examples comprising vitamin D and magnesium (p.8, examples).

Naito et al. teaches phosphatidylethanolamine is used for treating depression (abstract).

Bormann et al. teaches phosphatidylserine is used for treating depression disorders (abstract).

Oberthur et al. teaches pantothenic acid (vitamin B5) fights depression (col.8 line 35-40).

The above references do not teach a method for treating depression or related disorders by administering the claimed composition. However, as demonstrated by the cited references, each of the claimed ingredients were well known in the art for their claimed purpose. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the known antidepressants in a method for treating/preventing depression with a reasonable expectation of success, given the known antidepressant characteristics of the components. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients in a method for treating depression, since they were each well known antidepressants, as evidenced by the cited references.

14. Claims 26, 30, 32, 35, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Naito, Bormann and Takeda Chem Ind Ltd (Derwent 1997-017294).

Applicant claims a method for treating and/or preventing depression and depression related disorders comprising orally administering a composition comprising (a) long chain polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) at least one compound selected from folate, vitamin B12, B6, magnesium, zinc. The omega-3 fatty acids are selected from eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) and the omega-6 fatty acids are selected from arachidonic acid (ARA) and dihomogamma linolenic acid (DGLA). The (c) portion contains both folate and vitamin B6. The composition further comprises at least one of carnitine, vitamin B1, B5, coenzyme Q10; further comprises at least one of vitamin C, E, lipoic acid, selenium salt or carotenoids; or further comprises vitamin D.

Horrobin teaches compositions for treating depression comprising DHA, ascorbic acid (vitamin C), beta carotene, vitamin B6, zinc, vitamin E and selenium (p.7,Table 3). Specifically, Horrobin teaches DHA (omega 3 fatty acid) can treat depression in doses of at least 350 mg/day (p.4). EPA, linoleic acid (omega 6), dihomogamma linolenic (omega 6) and arachidonic acid are also added to the antidepressant composition at 250 – 2000 mg/day (p.6). The compositions further contain lipoic acid (p.6) and folic acid, described as valuable nutrients in depression (p.8). Horrobin provides examples comprising vitamin D and magnesium (p.8, examples).

Naito et al. teaches phosphatidylethanolamine is used for treating depression (abstract).

Bormann et al. teaches phosphatidylserine is used for treating depression disorders (abstract).

Takeda Chem Ind Ltd teaches carnitines and vitamin B1 are effective for treating depression (abstract).

The above references do not teach a method for treating depression or related disorders by administering the claimed composition. However, as demonstrated by the cited references, each of the claimed ingredients were well known in the art for their claimed purpose. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the known antidepressants in a method for treating/preventing depression with a reasonable expectation of success, given the known antidepressant characteristics of the components. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients in a method for treating depression, since they were each well known antidepressants, as evidenced by the cited references.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
August 20, 2002

LEON B. LANKFORD, JR.
PRIMARY EXAMINER